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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/787,866	03/22/2001	Maria Emanuel Ryan	178-261 PCT/	8018
23869	7590	06/22/2004	EXAMINER	
HOFFMANN & BARON, LLP 6900 JERICHO TURNPIKE SYOSSET, NY 11791			DELACROIX MUIRHEI, CYBILLE	
			ART UNIT	PAPER NUMBER
			1614	

DATE MAILED: 06/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/787,866	RYAN ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Cybille Delacroix-Muirheid	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 13 February 2004.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1,3-6,11-17,35 and 37-53 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) 37-40, 42-45, 48-51 is/are allowed.
- 6) Claim(s) 1,6,14,16 and 17 is/are rejected.
- 7) Claim(s) 3-5,11-13,15,35,41,46,47,52 and 53 is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All
  - b) Some \*
  - c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____ .
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ .	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
	6) <input type="checkbox"/> Other: _____ .

***Detailed Action***

The following is responsive to Applicant's amendment received Feb. 13, 2004.

Claims 2, 7-10, 18-34 and 36 are cancelled. New claims 37-53 are added.

Claims 1, 3-6, 11-17, 35, 37-53 are currently pending.

Applicant's claim for priority to PCT/US99/22354 filed Sep. 28, 1999 and provisional application 60/102,056 filed Sep. 28, 1998 is acknowledged.

The previous objection set forth in paragraph 3 of the office action mailed Jan. 29, 2003 **is withdrawn** in view of Applicant's amendment and the remarks contained therein.

The previous claim rejection under 35 USC 112, paragraph 2, set forth in paragraphs 4-5 of the office action mailed Jan. 29, 2003 **is withdrawn** in view of Applicant's amendment and the remarks contained therein.

The previous claim rejection under 35 USC 103(a) set forth in paragraph 4 of the office action mailed Sep. 10, 2003 **is withdrawn** in view of Applicant's amendment and the remarks contained therein.

However, Applicant's arguments traversing the previous rejection under 35 USC 102(b) set forth on pages 6-8 of the office action mailed Sep. 10, 2003 have been considered but are not found to be persuasive. Said rejection is maintained essentially for the reasons given previously in the office action mailed Sep. 10, 2003 with the following additional comment:

In the remarks, Applicant has indicated that claim 1 has been amended to incorporate the limitation that the administered tetracycline be a —non-antimicrobial—

tetracycline derivative. However, Applicant does not discuss how such a limitation distinguishes the claimed method from the method disclosed in the Smirnov abstract.

According to 37 CFR 1.111(b) and (c):

(b) In order to be entitled to reconsideration or further examination, the applicant or patent owner must reply to the Office action. The reply by the applicant or patent owner must be reduced to a writing which distinctly and specifically points out the supposed errors in the examiner's action and must reply to every ground of objection and rejection in the prior Office action. The reply must present arguments pointing out the specific distinctions believed to render the claims, including any newly presented claims, patentable over any applied references. A general allegation that the claims define a patentable invention without specifically pointing out how the language of the claims patentably distinguishes them from the references does not comply with the requirements of this section.

(c) In amending in reply to a rejection of claims in an application or patent under reexamination, the applicant or patent owner must clearly point out the patentable novelty which he or she thinks the claims present in view of the state of the art disclosed by the references cited or the objections made. The applicant or patent owner must also show how the amendments avoid such references or objections.

In this case, the Examiner respectfully submits that Applicant has not clearly pointed out the patentable novelty, which Applicant believes distinguishes the claimed method over the prior art of record, i.e. Smirnov abstract. The remarks generally state that the claims have been amended to include a new limitation which defines the patentable invention. In the absence of further arguments, the rejection is respectfully maintained.

#### ***New Ground(s) of Rejection***

#### ***Claim Objection(s)***

1. Claims 1, 15, 16, 35, 41, 46, 47, 52, 53 are objected to because of the following informalities: in claims 1, 35, 41, 47 and 53, line 2, the phrase –in need thereof—should be added after “mammal.” In claims 46 and 52, lines 2-3, before “mammal”, the “a”

should be cancelled and replaced with –the--. In claim 15, page 6, line 6, the limitation “and unacceptable” should be deleted. In claim 16, page 8, line 13, the limitation “and unacceptable” should be deleted. Appropriate correction is required.

***Claim Rejection(s)—35 USC 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 6, 16-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
3. In claim 6, line 5, the limitation “its derivatives” is vague and indefinite for several reasons. First, one of ordinary skill in the art would not know to what compound “it” refers. Secondly, assuming that “it” refers to “12a deoxycycline”, one of ordinary skill in the art would not be readily apprised of all derivatives of 12a deoxycycline that are encompassed by the limitation “its derivatives.” The specification does not provide an explanation of the derivatives, which Applicant regards as the invention. Therefore, the metes and bounds of patent protection desired are unclear.
4. Claim 16 recites the limitation “when R4 is ... N-NH-alkyl or NH-alkyl” in line 15 (page 8). There is insufficient antecedent basis for this limitation in the claim.
5. Claim 16 recites the limitation “when R4 is N-NH-alkyl” in line 19 (page 8). There is insufficient antecedent basis for this limitation in the claim.
6. Claim 16 recites the limitation “when R4 is NH-alkyl” in line 21 (page 8). There is insufficient antecedent basis for this limitation in the claim.

7. Claim 16 recites the limitation "when R4 is NH-alkyl" in line 26 (page 8). There is insufficient antecedent basis for this limitation in the claim.

8. Claim 17 is vague and indefinite because at page 10, it recites the administration of compounds represented by a "General Formula (II)". However, there are four subgeneric compounds (J-M) listed. The same applies to the recitation of a "General Formula (IV) at page 12 of claim 17. Please note that there are two subgeneric structures (O-P) listed. One of ordinary skill in the art would not know to which compounds these formulae refer. Moreover, it is not clear why more than one compound is listed for a single general formula. Further clarification and/or correction is respectfully requested.

***Conclusion***

Claims 1, 6, 14, 16, 17 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cybille Delacroix-Muirheid whose telephone number is 571-272-0572. The examiner can normally be reached on Mon-Fri from 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached at 571-272-0953. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

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Status information for unpublished applications is available through Private PAIR only.  
For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CDM



June 19, 2004



Cybille M

Cybille Delacroix-Muirheid  
Patent Examiner Group 1600